REMARKS

Claims 40-43 and 50-73 are currently pending in the present application.

Applicants have amended claims 55, 56, 58 and 61 for clarification purposes only. These claims have been amended to recite that the housing is manually deformable from a first geometrical housing configuration to a second geometrical housing configuration to effect release of the plunger. Support for the amendment to claims 55, 56, 58 and 61 may be found through out the specification, for example, on page 18, lines 28-32. Claim 66 has been amended to clarify that at least a portion of the infusion set is removably received within the device housing. Claim 67 has been amended to independent form. New claim 73 has been added. Support for the amendments and the newly added claim may be found in the previously filed claims and in the specification. No new matter has been added.

Applicants respectfully remind the Examiner of the injector device assembly demonstrated in the interview conducted November 27, 2007. During that interview, Applicants' representatives demonstrated the device and emphasized the following features present in the device:

1. Preloading of an infusion set within the device housing that is provided to the patient in a ready-to-insert configuration to simplify use by the patient by avoiding any manipulation of infusion set onto the inserter by the patient, and
2. Containment in a secured and stable fashion of the infusion set within the device housing and the cover for delivery to the patient. The same device housing that contains the infusion set is also itself manually deformable to effect release of the plunger after the cover has been removed.

Independent claims 55, 56, 58, 61 and 66 herein have already been amended to recite a cover connectable to the housing as was suggested by the Examiner during the interview. As previously presented, claims 55, 56, 58 and 61 further recite a manually deformable housing to effect release of the plunger. Each of these claims also requires an infusion set. Claim 66 requires an infusion set that is at least partially positioned within the device housing and removable therefrom. The Examiner has shown no art that discloses these features.

In the present Office Action, the Examiner's rejections continue the pattern of rejecting Applicants' claims over art that relates to devices that are completely different from claimed invention. As discussed in further detail below, Miskinyar is another example of an innoculator where there is no separable infusion set provided mounted in the device housing or where the housing is not itself manually deformable. Safabash (a CIP of the Funderburk reference previously cited) is another example of an inserter that does not even contemplate a cover connectable to the device housing. Further, Safabash fails to teach or suggest that the device housing itself is manually deformable.

Applicants respectfully request reconsideration.

I. Interview Summary

Applicants thank the Examiner for sending the interview summary to indicate that the Supplemental Amendment filed on December 7, 2007 had been considered by the Examiner in the Office Action mailed January 23, 2008. On page 2 of the Office Action, the Examiner indicated that the Office Action was responsive to the communication filed on October 31, 2007. Applicants thank the Examiner for making the clarification that the Supplemental Amendment filed on December 7, 2007 had been considered.

II. Claim Rejections Under 35 U.S.C. § 102

A. Claims 55, 57, 60, 66 and 70-72

Claims 55, 57, 60, 66 and 70-72 have been rejected under 35 U.S.C. 102(b) as being anticipated by Miskinyar (U.S. 5,527,287).

Applicants respectfully traverse the rejection of claims 55, 57, 60, 66 and 70-72 as being anticipated by Miskinyar. Applicants' independent claim 55 requires an infusion set and a housing that is manually deformable to effect release of the plunger. Claim 55 further recites that the housing is manually deformable from a first geometric housing configuration to a second geometric housing configuration to effect release of the plunger. Claim 66 requires a removable infusion set and a cover removably connected to a front end portion of the housing and covering an opening defined in the front end portion of the housing wherein the cover receives a part of the infusion set.

An insertion set is clearly not taught or suggested by Miskinyar. Miskinyar further clearly fails to teach or suggest a housing that is manually deformable to effect release of the plunger. In addition, Miskinyar fails to teach a housing that is manually deformable from a first geometric housing configuration to a second geometric housing configuration. With respect to claim 66, Miskinyar also fails to teach or suggest a cover that is connected to a front end portion of the housing where the cover receives a part of the infusion set and the infusion set is removable from the device.

Miskinyar is directed to a pre-charged, disposable syringe. As described in the specification, the device includes a housing 10 and an ampoule member 18. The device includes an actuator button 33 that is received in the central aperture of the cover 40. (See Col. 2, lines 50-51 and lines 62-66.) The actuator button 33 is enclosed within a protective cover 38 which seats against an annular rim 39 about the mid-portion of the housing 10. (Col. 3, lines 31-33.) In operation, the patient depresses the actuator button 33, breaking the detent of the plastic ring 56 and permitting the release of medication into the patient. (See Col. 4, lines 23-33.) The element 74 that the Examiner refers to as a housing of the infusion set is an ampoule 74 that is contained within the ampoule chamber 24. In fact, the ampoule 74 is formed by an elastic balloon which is received within and **sealed** to the inner walls of the ampoule chamber. (Col. 3, lines 60-64.) Miskinyar does not teach or suggest any removable infusion set for placement by an injector. Miskinyar is directed a preloaded automatic disposable syringe. The syringe includes a button, completely separate from the device housing, where the separate button is used to release the medication into the patient. The release is not effected by the manual deformation of the housing itself from a first geometrical housing configuration to a second geometrical housing configuration. Clearly, Miskinyar fails to teach or suggest a manually deformable housing as claimed in claim 55. Further, Miskinyar fails to teach or suggest an infusion set that is received at least partially by a cover and removable from the device housing device as claimed in claim 66.

Therefore, Applicants respectfully request that the rejection of claims 55, 57, 60, 66 and 70-72 under 35 U.S.C. 102(b) be withdrawn.

B. Claims 55-57, 60-64, 66, and 69-72

Claims 55-57, 60-64, 66, and 69-72 have been rejected under 35 U.S.C. 102(e) as being anticipated by Safabash et al. (U.S. 6,293,925).

Applicants respectfully traverse the rejection of claims 55-57, 60-64, 66, and 69-72 as being anticipated by Safabash. Independent claims 55, 56, 61 and 66 each require a cover connected to a portion of a device **housing** and covering an end of the device housing. Claims 55, 56, 61 and 66 also require a manually deformable **housing** to effect release of the plunger. In other words, Applicants' claims 55, 56, 61 and 66 require that the cover be connected to a portion of the same element that also effects release of the plunger. Safabash clearly fails to teach or suggest a cover connected to a portion of the device housing and further fails to teach or suggest a manually deformable housing to effect release of the plunger.

According to the Examiner, Safabash teaches a cover 414. According to the specification, the element 414 is a piercing member guard (or needle guard) that the user presses against the seat of the piercing member hub 408 (or needle hub) and the insertion set 400 in the cavity 514 of the carrier body 504. (Col. 19, lines 27-30.) As shown in FIG. 40d, the user removes the piercing member guard 414 (normally by twisting) to expose the piercing member 402 while maintaining the insertion set 400 within the carrier body 504. (Col. 19, lines 42-45.) Clearly, the guard 414 of Safabash is only a needle cover that is secured over the needle of the separable insertion set 400 only and is not connected to the device housing. Further, Safabash teaches a release button 508. As shown in FIG. 40f, the user depresses the release button 508 to release the insertion set from the cavity 514 of the carrier body 504. (Col. 19, lines 53-55.) As clearly shown in FIGS. 40e-40g, it is the button 508 that is depressed to release the infusion set. As shown in FIG. 40e, the button 508 is upstanding from the housing, in 40f, the button 508 is depressed as indicated by the large arrow and the infusion set is released (40g). The shape of the barrel of the housing does not change. In other words, Safabash does not teach or suggest a manually deformable **housing**.

The device shown in Safabash also does not provide secure containment for the insertion set. The purpose of the Safabash cover is completely different and serves only to

cover the needle. Safabash clearly fails to teach or suggest a cover where the cover is connected to the device housing. Safabash also clearly fails to teach or suggest a manually deformable housing where the housing itself is deformable from a first geometrical housing configuration to a second geometrical housing configuration to effect release of the plunger.

Therefore, Applicants respectfully request that the rejection of claims 55-57, 60-64, 66, and 69-72 under 35 U.S.C. 102(e) be withdrawn.

IV. Claim Rejections Under 35 U.S.C. § 103

A. Claims 58 and 59

Claims 58 and 59 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Safabash and further in view of Teeple, Jr. (U.S. 5,807,316). Teeple has been cited for encoding the shelf life on a device.

Applicants respectfully traverse the rejection of claims 58 and 59. Safabash has been discussed above and clearly fails to teach or suggest a cover removably secured to the device housing and the manually deformable device housing. Teeple is directed to a method and an apparatus for preparing and administering intravenous anesthesia infusions. (Abstract) Teeple fails to make up the deficiencies of Safabash.

Therefore, Applicants respectfully request that the rejection of claim 58 under 35 U.S.C. 103(a) be withdrawn.

V. Allowable Subject Matter

Applicants kindly thank the Examiner for indicating that claims 40-43, 51-54 and 65 are allowed. Applicants also thank the Examiner for indicating that claims 67 and 68 would be allowable if rewritten in independent form. Claim 67 has been rewritten in independent form including all the limitations of the base claim and any intervening claim.

VI. SUMMARY

It is respectfully asserted that the claims properly define the invention and that the invention is both novel and non-obvious. Allowance of the present claims is earnestly solicited.

Should the Examiner wish to discuss any of the above submissions in more detail, the Examiner is asked to please call the undersigned at the telephone number listed below.

Respectfully submitted,

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Date

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